Complete Summary

GUIDELINE TITLE

Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Chronic Conditions. Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control. London (UK): Royal College of Physicians; 2006. 215 p. [386 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Tuberculosis

Note: The guideline considers both active clinical disease and latent infections caused by *Mycobacterium tuberculosis* complex (*Mycobacterium tuberculosis*, *Mycobacterium africanum*, *Mycobacterium bovis)*

GUIDELINE CATEGORY

Diagnosis
Management
Prevention

Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Pediatrics
Preventive Medicine
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide a user-friendly, clinical, evidence-based guideline for the National Health Service in England and Wales that:

- Offers best practice advice for tuberculosis (TB)
- Is based on best published evidence and expert consensus
- Takes into account patient choice and informed decision-making
- Defines the major components of the care provision for tuberculosis such as the diagnosis and management of both latent and active TB, and measures for its prevention and control
- Indicates areas suitable for clinical audit
- Details areas of uncertainty or controversy requiring further research
- Provides a choice of guideline versions for differing audiences (full version, short version, quick reference guide, and public version) in electronic or printed format

TARGET POPULATION

- Adults and children with clinical disease caused by *Mycobacterium tuberculosis* complex (*Mycobacterium tuberculosis*, *Mycobacterium africanum*, *Mycobacterium bovis)*, including people with human immunodeficiency virus (HIV)
- Adults and children with latent infection with *Mycobacterium tuberculosis* complex but not clinical disease, including people with HIV
- People at increased risk of infection by *Mycobacterium tuberculosis* complex (e.g., recent arrivals and returns from high prevalence areas, household

contacts of respiratory tuberculosis [TB], homeless people living on the street, HIV infected persons)
- Close contacts of people with TB infection

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Diagnosing latent tuberculosis (TB)
    - Mantoux testing
    - Interferon-gamma immunological testing
2. Diagnosing active tuberculosis
    - Posterior-anterior chest x-ray
    - Multiple sputum samples for microscopy and culture
    - Site-specific investigations for non-respiratory TB (x-ray, computed tomography, magnetic resonance imaging, ultrasound, echocardiogram, intravenous urography, biopsies, culture)
3. Use of rapid diagnostic tests (molecular methods, automated liquid culture)

Management of Active TB

1. Drug treatment with standard regimen (6 months of isoniazid and rifampicin supplemented in the first 2 months with pyrazinamide and ethambutol) (Note: Other regimens are considered for spinal TB, meningeal TB, and drug-resistant TB)
2. Adjunctive glucocorticoid treatment in patients with meningeal TB
3. Consideration of dosing schedules and combination tablets
4. Infection control and isolation procedures in hospital settings for cases of respiratory and drug-resistant TB (e.g., negative-pressure rooms, single rooms vented to outside, wards)
5. Spinal fusion for spinal TB (not recommended routinely)
6. Testing for central nervous system involvement (brain scan, lumbar puncture)
7. Monitoring for adherence and treatment completion and interventions to improve adherence, such as reminder letters, counselling, and home visits
8. Use of directly observed therapy
9. Risk assessment of patients for drug resistance and tests for rifampicin resistance

Management of Latent TB

1. Consideration of drug treatment in specific populations based on results of screening tests
2. Drug treatment for latent TB (regimens consisting of isoniazid and rifampicin)
3. Provision of "inform and advise" information in people eligible for treatment who decline treatment
4. Special considerations for neonates and children in close contact with people with sputum smear-positive TB

Prevention/Screening

1. Bacille Calmette-Guerin (BCG) vaccination

2. Active case finding through contact tracing
3. Screening of people at increased risk, including street homeless, new entrants to the country, healthcare workers, and prisoners and prison staff

MAJOR OUTCOMES CONSIDERED

- Diagnostic performance of tests for tuberculosis (TB) (sensitivity, specificity, speed)
- Cure rate
- Relapse rate associated with drug regimens
- Effectiveness of infection control measures on TB transmission
- Mortality and rate of severe residual disability
- Rate of treatment completion and treatment adherence
- Rate of drug resistance
- Efficacy of Bacille Calmette-Guerin (BCG) vaccination for preventing pulmonary TB disease, TB deaths, TB meningitis, laboratory-confirmed TB cases, and disseminated TB
- Case yields of latent tuberculosis infection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The information scientist developed a search strategy for each clinical question. Key words for the search were identified by the Guideline Development Group (GDG). Papers that were published or accepted for publication in peer-reviewed journals were considered as evidence by the GDG. Each clinical question dictated the appropriate study design that was prioritised in the search strategy but the strategy was not limited solely to these study types. Conference paper abstracts and non-English language papers were excluded from the searches. The research fellow identified titles and abstracts from the search results that appeared to be relevant to the question. Exclusion lists were generated for each question together with the rationale for the exclusion. The exclusion lists were presented to the GDG. Full papers were obtained where relevant. See Appendix A in the full version of the original guideline document for literature search details.

Literature searches were repeated for all of the evidence-based questions at the end of the GDG development process allowing any relevant papers published up until 30 November 2004 to be considered. The GDG agreed to make a special provision to extend this in one case where much new evidence was known to be forthcoming: interferon-gamma testing for latent tuberculosis, where published evidence was considered up to and including 21 July 2005.

The health economist performed supplemental literature searches to obtain additional data for modelling.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Intervention Studies

1^{++} High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1^{+} Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1^{-} Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2^{++} High-quality systematic reviews of case–control or cohort studies. High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2^{+} Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2^{-} Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytical studies (for example, case reports, case series)

4 Expert opinion, formal consensus

Levels of Evidence for Studies of the Accuracy of Diagnostic Tests

Ia Systematic review (with no or minor variations in the directions and degrees of results between studies) of level-1 studies, which are studies that use:

- A blind comparison of the test with a validated reference standard (gold standard)
- A sample of patients that reflects the population to whom the test would apply

Ib Level-1 studies

II Level-2 studies, which are studies that have only one of the following:

- The population is narrow (the sample does not reflect the population to whom the test would apply).

- A poor reference standard is used (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference').
- The comparison between the test and reference standard is not blind.
- The study is a case-control study.

Systematic reviews of level-2 studies

III Level-3 studies, which are studies that have at least two of the features listed for level-2 studies *or*

Systematic reviews of level-3 studies

IV Expert committee reports, opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research, or 'first principles'

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Critically Appraising the Evidence

The research fellow or health economist, as appropriate, critically appraised the full papers obtained from the literature search. In general no formal contact was made with authors; however, there were ad hoc occasions when this was required in order to clarify specific details. Critical appraisal checklists were compiled for each full paper. One research fellow undertook the critical appraisal and data extraction. The evidence was considered carefully by the Guideline Development Group (GDG) for accuracy and completeness.

All procedures are fully compliant with the:

- National Institute for Health and Clinical Evidence (NICE) methodology as detailed in the Technical Manual
- National Collaborating Centre for Chronic Conditions (NCC-CC) Quality Assurance document & Systematic Review paper available at http://www.rcplondon.ac.uk/college/ceeu/ncccc_index.htm.

Distilling and Synthesising the Evidence and Writing Recommendations

The evidence from each full paper was distilled into an evidence table and synthesised into evidence statements before being presented to the GDG. This evidence was then reviewed by the GDG and used as a basis upon which to formulate recommendations. Evidence tables are available at www.rcplondon.ac.uk/. The evidence statements and recommendations were graded (see "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations"). The level of evidence and classification of recommendations were also included for diagnostic studies.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guideline Development Group

The Guideline Development Group (GDG) met monthly for 15 months (2004 to 2005) and comprised a multidisciplinary team of professionals, service users, carers, and user organisation representatives who were supported by the technical team.

The GDG membership details including patient representation and professional groups are detailed in the GDG membership section at the front of the original guideline document.

Reviewing Evidence and Grading Recommendations

Evidence was reviewed by the GDG and used as a basis upon which to formulate recommendations. The evidence statements and recommendations were graded (see "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations"). The level of evidence and classification of recommendations were also included for diagnostic studies.

Agreeing the Recommendations

The sign-off workshop employed formal consensus techniques to:

- Ensure that the recommendations reflected the evidence base
- Approve recommendations based on lesser evidence or extrapolations from other situations
- Reach consensus recommendations where the evidence was inadequate
- Debate areas of disagreement and finalise recommendations

The sign-off workshop also reached agreement on the following:

- Seven key priorities for implementation
- Eight key research recommendations
- Five algorithms

In prioritising key recommendations for implementation, the sign-off workshop also took into account the following criteria:

- High clinical impact
- High impact on reducing variation
- More efficient use of National Health Service resources
- Allowing the patient to reach critical points in the care pathway more quickly

The audit criteria provide suggestions of areas for audit in line with the key recommendations for implementation.

Writing the Guideline

The first draft version of the guideline was drawn up by the technical team in accord with the decision of the GDG.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations on Interventions

A At least one meta-analysis, systematic review, or randomised controlled trial (RCT) that is rated as 1^{++}, and is directly applicable to the target population, *or*
A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1^{+}, is directly applicable to the target population, and demonstrates overall consistency of results, *or*
Evidence drawn from a NICE technology appraisal

B A body of evidence that includes studies rated as 2^{++}, is directly applicable to the target population, and demonstrates overall consistency of results, *or*
Extrapolated evidence from studies rated as 1^{++} or 1^{+}

C A body of evidence that includes studies rated as 2^{+}, is directly applicable to the target population, and demonstrates overall consistency of results, *or*
Extrapolated evidence from studies rated as 2^{++}

D Evidence level 3 or 4, *or*
Extrapolated evidence from studies rated as 2^{+}, *or*
Formal consensus

D(GPP) A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group *or* extrapolated from level 2 clinical evidence, supplemented with health-economic modelling

Classification of Recommendations on Diagnostic Tests

A(DS) Studies with level of evidence Ia or Ib

B(DS) Studies with level of evidence II

C(DS) Studies with level of evidence III

D(DS) Studies with level of evidence IV

COST ANALYSIS

Health Economic Evidence

Due to the appointment of the health economist midway through the guideline development, the areas for health economic modelling were considered after the formation of the clinical questions. The health economist reviewed the clinical questions to consider the potential application of health economic modelling, and these priorities were agreed with the Guideline Development Group (GDG).

The health economist performed supplemental literature searches to obtain additional data for modelling. Assumptions and designs of the models were explained to and agreed by the GDG members during meetings, and they also commented on subsequent revisions.

Evidence for the cost-effectiveness of various interventions and practices are reviewed in the full version of the original guideline document.

A costing report and a costing template are also available as separate documents (See "Availability of Companion Documents"). The costing report looks at the resource impact of implementing the guideline in England. The costing template allows users to tailor the local cost impact of implementation to their circumstances.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (The full guideline, National Institute for Clinical Excellence (NICE) guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG).
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions are provided at the end of the "Major Recommendations" for the levels of the evidence for intervention studies (1^{++} to 4), the levels of the evidence for studies of the accuracy of diagnostic tests (Ia to IV), the classification of recommendations for interventions (A, B, C, D, D[GPP]), and classification of recommendations on diagnostic tests (A[DS], B[DS], C[DS], D[DS]).

Diagnosis and Treatment

Diagnosis

Diagnosing Latent Tuberculosis

D - To diagnose latent tuberculosis (TB):

- Mantoux testing should be performed in line with the "Green Book" (Department of Health, 2006).
- Those with positive results (or in whom Mantoux testing may be less reliable) should then be considered for interferon-gamma immunological testing, if available.
- If testing is inconclusive, the person should be referred to a TB specialist (see "Management of Latent Tuberculosis" below).

Diagnosing Active Tuberculosis

To diagnose active respiratory TB:

- **C(DS)** - A posterior-anterior chest x-ray should be taken; chest x-ray appearances suggestive of TB should lead to further diagnostic investigation.
- **C(DS)** - Multiple sputum samples (at least three, with one early morning sample) should be sent for TB microscopy and culture for suspected respiratory TB before starting treatment if possible or, failing that, within seven days of starting.
- **B(DS)** - Spontaneously produced sputum should be obtained if possible; otherwise induction of sputum or bronchoscopy and lavage should be used.
- **B(DS)** - In children unable to expectorate sputum, induction of sputum should be considered if it can be done safely, with gastric washings considered as third line.
- **D(GPP)** - If there are clinical signs and symptoms consistent with a diagnosis of TB, treatment should be started without waiting for culture results (see section titled "Drug Treatment" under "Management of Respiratory Tuberculosis" below).
- **D(GPP)** - The standard recommended regimen should be continued in patients whose subsequent culture results are negative.
- **D(GPP)** - Samples should be sent for TB culture from autopsy samples if respiratory TB is a possibility.

To diagnose active non-respiratory TB:

- **B(DS)** - Advantages and disadvantages of both biopsy and needle aspiration should be discussed with the patient, with the aim of obtaining adequate material for diagnosis
- **D(GPP)** - If non-respiratory TB is a possibility, part or all of any of the following samples should be placed in a dry pot (and not all placed in formalin) and sent for TB culture:
    - Lymph node biopsy
    - Pus aspirated from lymph nodes
    - Pleural biopsy
    - Any surgical sample sent for routine culture
    - Any radiological sample sent for routine culture
    - Histology sample

    - Aspiration sample
    - Autopsy sample
- **D(GPP)** - Microbiology staff should routinely perform TB culture on the above samples (even if it is not requested).
- **C(DS)** - The appropriate treatment regimen should be started without waiting for culture results if the histology and clinical picture are consistent with a diagnosis of TB (see "Management of Respiratory Tuberculosis" and "Management of Non-Respiratory Tuberculosis" below)
- **D(GPP)** - All patients with non-respiratory TB should have a chest x-ray to exclude or confirm coexisting respiratory TB; in addition, tests described in the table below should be considered
- **D(GPP)** - The appropriate drug regimen (see "Management of Respiratory Tuberculosis," "Management of Non-Respiratory Tuberculosis," and " Risk Assessment and Infection Control in Drug-Resistant TB" below) should be continued even if subsequent culture results are negative.

Table. Suggested site-specific investigations in the diagnosis and assessment of nonrespiratory TB

Site	Imaging	Biopsy	Culture
Lymph node		• Node	• Node or aspirate
Bone/joint	• Plain x-ray and computed tomography (CT) • Magnetic resonance imaging (MRI)	• Site of disease	• Biopsy or para-spinal abscess • Site or joint fluid
Gastrointestinal	• Ultrasound • CT abdomen	• Omentum • Bowel	• Biopsy • Ascites
Genitourinary	• Intravenous urography • Ultrasound	• Site of disease	• Early morning urine • Site of disease • Endometrial curettings
Disseminated	• High resolution CT thorax • Ultrasound abdomen	• Lung • Liver • Bone marrow	• Bronchial wash • Liver • Bone marrow • Blood
Central nervous system	• CT brain • MRI	• Tuberculoma	• Cerebrospinal fluid (CSF)
Skin		• Site of disease	• Site of disease
Pericardium	• Echocardiogram	• Pericardium	• Pericardial fluid

Table. Suggested site-specific investigations in the diagnosis and assessment of nonrespiratory TB			
Site	**Imaging**	**Biopsy**	**Culture**
Cold/liver abscess	• Ultrasound	• Site of disease	• Site of disease

Rapid Diagnostic Tests

D(GPP) - Rapid diagnostic tests for *Mycobacterium tuberculosis* complex *(M. tuberculosis, M. bovis, M. africanum)* on primary specimens should be used only if:

- Rapid confirmation of a TB diagnosis in a sputum smear-positive person would alter their care, or
- Before conducting a large contact-tracing initiative

B(DS) - Clinicians should still consider a diagnosis of non-respiratory TB if rapid diagnostic tests are negative, for example in pleural fluid, CSF, and urine.

D(GPP) - Clinical signs and other laboratory findings consistent with TB meningitis (see "Meningeal TB" under "Management of Non-respiratory TB" below) should lead to treatment, even if a rapid diagnostic test is negative, because the potential consequences for the patient are severe.

D(GPP) - Before conducting a large contact-tracing initiative (for example, in a school or hospital), the species of *mycobacterium* should be confirmed to be *M. tuberculosis* complex by rapid diagnostic tests on microscopy- or culture-positive material. Clinical judgement should be used if tests are inconclusive or delayed.

D(GPP) - If a risk assessment suggests a patient has multi-drug resistant (MDR) TB (see "Risk Assessment and Infection Control in Drug-Resistant TB" below):

- Rapid diagnostic tests should be conducted for rifampicin resistance
- Infection control measures and treatment for MDR TB should be started as described in "Risk Assessment and Infection Control in Drug-Resistant TB," pending the result of the tests.

D(GPP) - Rapid diagnostic tests for *M. tuberculosis* complex identification should be conducted on biopsy material only if:

- All the sample has been inappropriately placed in formalin, and
- Acid-fast bacilli (AFB) are visible on microscopy

D(GPP) - Clinical samples should ideally be sent for culture by automated liquid methods, bearing in mind that laboratories need a certain level of throughput to maintain quality control.

Management of Respiratory Tuberculosis

Drug Treatment

C - Once a diagnosis of active TB is made, the clinician responsible for care should refer the person with TB to a physician with training in, and experience of, the specialised care of people with TB. The TB service should include specialised nurses and health visitors. TB in children should be managed either by a paediatrician with experience and training in the treatment of TB, or by a general paediatrician with advice from a specialised physician. If these arrangements are not possible, advice should be sought from more specialised colleagues throughout the treatment period.

A six-month, four-drug initial regimen (six months of isoniazid and rifampicin supplemented in the first two months with pyrazinamide and ethambutol) should be used to treat active respiratory TB in:

- **A** - Adults not known to be human immunodeficiency virus (HIV)-positive
- **B** - Adults who are HIV-positive
- **B** - Children

This regimen is referred to as "standard recommended regimen" in this guideline.

C - Fixed-dose combination tablets should be used as part of any TB treatment regimen.

D(GPP) - A thrice-weekly dosing regimen should be considered for patients receiving directly observed therapy (DOT) (See "Improving Adherence: Directly Observed Therapy" below).

D(GPP) - A twice-weekly dosing regimen should not be used for the treatment of active TB.

Infection Control

The recommendations below deal with three levels of isolation for infection control in hospital settings:

- *Negative pressure rooms, which have air pressure continuously or automatically measured, as defined by NHS Estates* (NHS Estates, 2005)
- *Single rooms that are not negative pressure but are vented to the outside of the building*
- *Beds on a ward, for which no particular engineering standards are required*

D(GPP) - All patients with TB should have risk assessments for drug resistance and for HIV. If risk factors for MDR TB are present, see "Risk Assessment and Infection Control in Drug-Resistant TB" below for recommendations on infection control.

D(GPP) - Unless there is a clear clinical or socioeconomic need, such as homelessness, people with TB at any site of disease should not be admitted to hospital for diagnostic tests or for care.

D(GPP) - If admitted to hospital, patients with suspected respiratory TB should be given a single room.

D(GPP) - Patients with respiratory TB should be separated from immunocompromised patients, either by admission to a single room on a separate ward, or in a negative pressure room on the same ward.

D(GPP) - Any visitors to a child with TB in hospital should be screened as part of contact tracing, and kept separate from other patients until they have been excluded as the source of infection.

D(GPP) - Smear-positive TB patients without risk factors for MDR TB (see "Risk Assessment and Infection Control in Drug-Resistant TB" below) should be cared for in a single room, until:

- They have completed two weeks of the standard treatment regimen (see "Drug Treatment" under "Management of Respiratory Tuberculosis" above) , or
- They are discharged from hospital

D(GPP) - Aerosol-generating procedures such as bronchoscopy, sputum induction, or nebuliser treatment should be carried out in an appropriately engineered and ventilated area for:

- All patients on an HIV ward, regardless of whether a diagnosis of TB has been considered
- All patients in whom TB is considered a possible diagnosis, in any setting

D(GPP) - Healthcare workers caring for people with TB should not use masks, gowns, or barrier nursing techniques unless:

- MDR TB is suspected
- Aerosol-generating procedures are being performed

When such equipment is used, the reason should be explained to the person with TB. The equipment should meet the standards of the Health and Safety Executive. See "Infection Control" under "Risk Assessment and Infection Control in Drug-Resistant TB" below for further details of MDR TB infection control.

D(GPP) - TB patients admitted to a setting where care is provided for HIV-positive or other immunocompromised patients should be considered infectious and, if sputum smear-positive at admission, should stay in a negative pressure room until:

1. The patient has had at least two weeks of appropriate multiple drug therapy, *and*
2. If moving to accommodation (inpatient or home) with HIV-positive or immunocompromised patients, the patient has had at least three negative microscopic smears on separate occasions over a 14-day period, *and*
3. The patient is showing tolerance to the prescribed treatment and an ability and agreement to adhere to treatment, *and either*
4. Any cough has resolved completely, *or*
5. There is definite clinical improvement on treatment, for example remaining afebrile for a week.

For people who were sputum smear negative at admission (that is, three negative samples were taken on separate days; samples were spontaneously produced sputum if possible, or obtained by bronchoscopy or lavage if sputum samples were not possible): *all* of 1, 2, 3 and 5 above should apply.

D(GPP) - Inpatients with smear-positive respiratory TB should be asked (with explanation) to wear a surgical mask whenever they leave their room until they have had two weeks' drug treatment.

Management of Non-respiratory Tuberculosis

Meningeal Tuberculosis

Patients with active meningeal TB should be offered:

- **D(GPP)** - A treatment regimen, initially lasting for 12 months, comprising isoniazid, pyrazinamide, rifampicin and a fourth drug (for example, ethambutol) for the first two months, followed by isoniazid and rifampicin for the rest of the treatment period
- A glucocorticoid at the normal dose range
    - **A** - Adults equivalent to prednisolone 20–40 mg if on rifampicin, otherwise 10 to 20 mg
    - **D(GPP)** - Children equivalent to prednisolone 1–2 mg/kg, maximum 40 mg

  with gradual withdrawal of the glucocorticoid considered, starting within 2–3 weeks of initiation. **D(GPP)**

Clinicians prescribing treatment for active meningeal TB should consider as first choice:

- **B** - A daily dosing schedule
- **D** - Using combination tablets

Peripheral Lymph Node Tuberculosis

For patients with active peripheral lymph node tuberculosis, the first choice of treatment should:

- **B** - Be the standard recommended regimen (see "Drug Treatment" under "Management of Respiratory Tuberculosis" above for further details)
- **B** - Use a daily dosing schedule
- **D** - Include combination tablets

D(GPP) - Patients with active peripheral lymph node TB who have had an affected gland surgically removed should still be treated with the standard recommended regimen.

D(GPP) - Drug treatment of peripheral lymph node TB should normally be stopped after six months, regardless of the appearance of new nodes, residual nodes, or sinuses draining during treatment.

Bone and Joint Tuberculosis: Drug Treatment

The standard recommended regimen should be planned and started in people with:

- **B** - Active spinal TB
- **C** - Active TB at other bone and joint sites

Clinicians prescribing treatment for active bone and joint tuberculosis should consider as first choice:

- **B** - A daily dosing schedule
- **D** - Using combination tablets

See "Drug Treatment" under "Management of Respiratory Tuberculosis" above for details.

D(GPP) - CT or MR scan should be performed on patients with active spinal TB who have neurological signs or symptoms. If there is direct spinal cord involvement (for example, a spinal cord tuberculoma), management should be as for meningeal TB (see "Meningeal Tuberculosis" above).

Bone and Joint Tuberculosis: Routine Therapeutic Surgery

B - In patients with spinal TB, anterior spinal fusion should not be performed routinely.

D(GPP) - In patients with spinal TB, anterior spinal fusion should be considered if there is spinal instability or evidence of spinal cord compression.

Pericardial Tuberculosis

For patients with active pericardial TB, the first choice of treatment should:

- **B** - Be the standard recommended regimen (see "Drug Treatment" under "Management of Respiratory Tuberculosis" above)
- **B** - Use a daily dosing schedule
- **D** - Include combination tablets

In addition to anti-TB treatment, patients with active pericardial TB should be offered:

- **A** - For adults, a glucocorticoid equivalent to prednisolone at 60 mg/day
- **D(GPP)** - For children, a glucocorticoid equivalent to prednisolone 1 mg/kg/day (maximum 40 mg/day), with gradual withdrawal of the glucocorticoid considered, starting within two to three weeks of initiation

Disseminated (Including Miliary) Tuberculosis

For patients with disseminated (including miliary) TB, the first choice of treatment should:

- **B** - Be the standard recommended regimen (see "Drug Treatment" under "Management of Respiratory Tuberculosis" above for details)
- **B** - Use a daily dosing schedule
- **D** - Include combination tablets

D(GPP) - Treatment of disseminated (including miliary) TB should be started even if initial liver function tests are abnormal. If the patient's liver function deteriorates significantly on drug treatment, advice on management options should be sought from clinicians with specialist experience of these circumstances.

D(GPP) - Patients with disseminated (including miliary) TB should be tested for central nervous system (CNS) involvement by:

- Brain scan (CT or MRI) and/or lumbar puncture for those with CNS signs or symptoms
- Lumbar puncture for those without CNS signs and symptoms

If evidence of CNS involvement is detected, treatment should be the same as for meningeal TB (see "Meningeal Tuberculosis" under "Management of Non-respiratory Tuberculosis" above).

Other Sites of Infection

For patients with:

- Active genitourinary TB, or
- Active TB of any site other than:
    - Respiratory system
    - CNS (typically meninges)
    - Peripheral lymph nodes
    - Bones and joints
    - Pericardium
    - Disseminated (including miliary) disease

The first choice of treatment should:

- **B** - Be the standard recommended regimen (see Drug Treatment" under "Management of Respiratory Tuberculosis" above for details)
- **B** - Use a daily dosing schedule
- **D** - Include combination tablets

Monitoring, Adherence, and Treatment Completion

Treatment Completion and Follow-up

D - Follow-up clinic visits should not be conducted routinely after treatment completion.

D(GPP) - Patients should be told to watch for symptoms of relapse and how to contact the TB service rapidly through primary care or a TB clinic. Key workers should ensure that patients at increased risk of relapse are particularly well informed about symptoms.

D(GPP) - Patients who have had drug-resistant TB should be considered for follow-up for 12 months after completing treatment. Patients who have had MDR TB should be considered for prolonged follow-up.

Improving Adherence: Directly Observed Therapy (DOT)

A - Use of DOT is not usually necessary in the management of most cases of active TB.

All patients should have a risk assessment for adherence to treatment, and DOT should be considered for patients who have adverse factors on their risk assessment, in particular:

- **B** - Street- or shelter-dwelling homeless people with active TB
- **D(GPP)** - Patients with likely poor adherence, in particular those who have a history of non-adherence

D(GPP) - Clinicians who are planning to start a patient on a course of DOT should consider ways to mitigate the environmental, financial, and psychosocial factors that may reduce adherence, including stability of accommodation, prescription charges, and transport. The setting, observer, and frequency of treatment should be arranged to be most practicable for the person with TB. The person with TB and his or her assigned key worker should be involved in deciding these arrangements. DOT should also be supported by frequent contact with the key worker (see "Improving Adherence: Non-pharmacological Strategies" below).

Improving Adherence: Non-pharmacological Strategies

D(GPP) - To promote adherence, patients should be involved in treatment decisions at the outset of treatment for active or latent TB. The importance of adherence should be emphasised during discussion with the patient when agreeing the regimen.

D(GPP) - The TB service should tell each person with TB who their named key worker is, and how to contact them. This key worker should facilitate education and involvement of the person with TB in achieving adherence.

TB services should consider the following interventions to improve adherence to treatment for active or latent TB if a patient defaults:

- **B** - Reminder letters in appropriate languages
- **B** - Health education counselling
- **B** - Patient-centred interview and health education booklet
- **D(GPP)** - Home visits
- **D(GPP)** - Patient diary
- **D(GPP)** - Random urine tests and other monitoring (for example, pill counts)

- **D(GPP)** - Information about help with paying for prescriptions
- **D(GPP)** - Help or advice about where and how to get social security benefits, housing and social services

D(GPP) - Pharmacies should make liquid preparations of anti-TB drugs readily available to TB patients who may need them—for example children and people with swallowing difficulties.

D(GPP) - TB services should assess local language and other communication needs and, if there is a demonstrated need, provide patient information accordingly. (Note: Patient information should be drawn from national high-quality resources if available; for examples, see www.hpa.org.ukor www.nks.nhs.uk)

Risk Assessment and Infection Control in Drug-Resistant TB

Risk Factors

C - A risk assessment for drug resistance should be made for each patient with TB, based on the risk factors listed below:

1. History of prior TB drug treatment; prior TB treatment failure
2. Contact with a known case of drug-resistant TB
3. Birth in a foreign country, particularly high-incidence countries as defined by the Health Protection Agency (HPA) on its website. (Go to www.hpa.org.uk and search for 'WHO country data TB".)
4. HIV infection
5. Residence in London
6. Age profile, with highest rates between ages 25 and 44
7. Male gender

D(GPP) - The TB service should consider the risk assessment for drug resistance and, if the risk is regarded as significant, urgent molecular tests for rifampicin resistance should be performed on smear-positive material or on positive cultures when they become available (see "Diagnosing Active Tuberculosis" above).

D(GPP) - Response to treatment should be closely monitored in patients at increased risk of drug resistance. If there is no clinical improvement, or if cultures remain positive after the fourth month of treatment ("treatment failure"), drug resistance should be suspected and treatment reviewed with a clinician experienced in the treatment of MDR TB. (See "Drug Treatment" under "Management of Respiratory Tuberculosis" above for details of the standard recommended regimen.)

Referral

D(GPP) - The options for organising care for people with MDR TB should be discussed with clinicians who specialise in this. The views of the patient should be sought and taken into account, and shared care should be considered.

Infection Control

D(GPP) - Patients with suspected or known infectious MDR TB who are admitted to hospital should be admitted to a negative pressure room. If none are available locally, the patient should be transferred to a hospital that has these facilities and a clinician experienced in managing complex drug-resistant cases. Care should be carried out in the negative pressure room until the patient is found to be non-infectious or non-resistant, and ideally until cultures are negative.

D(GPP) - Staff and visitors should wear FFP3 masks* (during contact with a patient with suspected or known MDR TB while the patient is considered infectious.

*Note: European standard EN149:2001; masks should meet the standards in the Health and Safety Executive's *Respiratory protective equipment at work: a practical guide HSG53*)

D(GPP) - Before the decision is made to discharge a patient with suspected or known MDR TB from hospital, secure arrangements for the supervision and administration of all anti-TB therapy should have been agreed with the patient and carers.

D(GPP) - The decision to discharge a patient with suspected or known MDR TB should be discussed with the infection control team, the local microbiologist, the local TB service, and the consultant in communicable disease control.

D(GPP) - Negative pressure rooms used for infection control in MDR TB should meet the standards of the Interdepartmental Working Group on Tuberculosis (Interdepartmental Working Group on Tuberculosis, 1998) and should be clearly identified for staff, for example by a standard sign. Such labelling should be kept up to date.

Treatment of Non-MDR TB Resistance

Patients with drug-resistant TB, other than MDR, should be under the care of a specialist physician with appropriate experience in managing such cases. First-choice drug treatment is set out in the table below.

Table. Recommended Regimens for Non-MDR Drug-resistant TB

Drug resistance	Initial Phase	Continuation Phase
S	2RHZE	4RH
H known prior to treatment	2RZSE	7RE
H found after starting treatment	2RZE	10RE
Z	2RHE	7RH
E	2RHZ	4RH
R (only if confirmed isolated resistance)	2HZE	16HE
S+H	2RZE	10RE
Other	Individualised	

Note on Drug Regimen Abbreviations: Drug regimens are often abbreviated to the number of months a phase of treatment lasts followed by letters for the drugs administered in that phase.

Table. Recommended Regimens for Non-MDR Drug-resistant TB		
Drug resistance	**Initial Phase**	**Continuation Phase**
H = isoniazid, R = rifampicin, Z = pyrazinamide, E = ethambutol, S = streptomycin. For example, 2HRZE/4HR is the standard regimen. 2HRE/7HR is 2 months of isoniazid, rifampicin, and ethambutol followed by 7 months of isoniazid and rifampicin.		

Management of Latent Tuberculosis

Treatment Regimens for Latent Tuberculosis Infection

D(GPP) - Treatment of latent TB infection should be considered for people in the following groups, once active TB has been excluded by chest x-ray and examination:

- People identified through screening who are:
    - Younger than 36 years (because of increasing risk of hepatotoxicity with age)
    - Any age with HIV
    - Any age and a healthcare worker

  and are either:

    - Mantoux positive (6 mm or greater), and without prior Bacille Calmette-Guerin (BCG) vaccination, *or*
    - Strongly Mantoux positive (15 mm or greater), interferon-gamma positive, and with prior BCG vaccination
- Children aged 1 to 5 years identified through opportunistic screening, to be:
    - Strongly Mantoux positive (15 mm or greater), *and*
    - Interferon-gamma positive (if this test has been performed), *and*
    - Without prior BCG vaccination
- People with evidence of TB scars on chest x-ray, and without a history of adequate treatment.

D(GPP) - People with HIV who are in close contact with people with sputum smear-positive respiratory TB should have active disease excluded and then be given treatment for latent TB infection. Mantoux testing may be unreliable in people with HIV. (Note: Close contacts may include a boyfriend or girlfriend and frequent visitors to the home of the index case, in addition to household contacts.)

D(GPP) - Treatment for latent TB infection should not be started in close contacts of people with sputum smear-positive MDR TB who are strongly Mantoux positive (15 mm or greater), as no regimen is of proven benefit, and only a small proportion of people infected will develop the disease. Long-term monitoring should be undertaken for active disease.

C - People who have agreed to receive treatment for latent TB infection should be started on one of the following regimens:

- **A** - Either six months of isoniazid (6H) or three months of rifampicin and isoniazid (3RH) for people aged 16–35 not known to have HIV
- **(GPP)** - Either six months of isoniazid (6H) or three months of rifampicin and isoniazid (3RH) for people older than 35 in whom treatment for latent TB infection is recommended (see above) and who are not known to have HIV **D**
- **A** - Six months of isoniazid (6H) for people of any age who have HIV
- **D(GPP)** - Six months of rifampicin (6R) for contacts, aged 35 or younger, of people with isoniazid-resistant TB

D(GPP) - People eligible for treatment of latent TB infection, but who decline to take this treatment, should be given "inform and advise" information about TB and have chest x-rays three and 12 months later.

D(GPP) - Neonates who have been in close contact with people with sputum smear-positive TB who have not received at least two weeks' anti-tuberculosis drug treatment should be treated as follows.

- The baby should be started on isoniazid 5 mg/kg for three months and then a Mantoux test performed after three months' treatment.
- If the Mantoux test is positive (6 mm or greater) the baby should be assessed for active TB (see section "Diagnosing Active Tuberculosis" above). If this assessment is negative, then isoniazid should be continued for a total of six months.
- If the test is negative (less than 6 mm), then isoniazid should be stopped and a BCG vaccination performed (see "BCG Vaccination" below).

D(GPP) - Children older than four weeks but younger than two years who have not had BCG vaccination and are in close contact with people with sputum smear-positive TB should be treated as follows.

- The child should be started on isoniazid 5 mg/kg and a Mantoux test performed.
- If the Mantoux test is positive (6 mm or greater), the child should be assessed for active TB (see section "Diagnosing Active Tuberculosis" above). If active TB is ruled out, full treatment for latent TB infection should be given (see recommendation below in this section)
- If the test is negative (less than 6 mm), then isoniazid should be continued and the Mantoux test repeated after six weeks.
- If the repeat test is negative, isoniazid may be stopped and BCG vaccination performed (see "BCG Vaccination" below).
- If the repeat test is positive (6 mm or greater), an interferon-gamma test should be conducted, if available. If this is positive, full treatment for latent TB infection should be given. If the test is not available, the child should be started on treatment for latent TB infection after a positive repeat Mantoux test result.

Contact tracing for children younger than two years when the index case is sputum smear positive is summarised in an algorithm (see section 12.2 in the original guideline document).

D(GPP) - BCG-vaccinated children aged older than four weeks but younger than two years, in close contact with people with sputum smear-positive respiratory TB, should be treated as follows.

- The child should have a Mantoux test. If this is positive (15 mm or greater), the child should be assessed for active TB (see "Diagnosing Active Tuberculosis" above). If active TB is excluded, then treatment for latent TB infection should be given (see next recommendation).
- If the result of the test is as expected for prior BCG (less than 15 mm), it should be repeated after six weeks.
- If the repeat test is also less than 15 mm, no further action is needed.
- If the repeat test becomes more strongly positive (15 mm or greater and an increase of 5 mm or more over the previous test), an interferon-gamma test should be conducted, if available. If this is positive, the child should be assessed for active TB (see section "Diagnosis of Active Tuberculosis" above). If the interferon-gamma test is not available, the child should be assessed for active TB after a positive repeat Mantoux test result. If active TB is excluded, treatment for latent TB infection should be given.

D(GPP) - For children requiring treatment for latent TB infection, a regimen of either three months of rifampicin and isoniazid (3RH) or six months of isoniazid (6H) should be planned and started, unless the child is known to be HIV positive, when 6H should be given.

D(GPP) - Healthcare workers should be aware that certain groups of people with latent TB are at increased risk of going on to develop active TB, including people who:

- Are HIV positive
- Are injecting drug users
- Have had solid organ transplantation
- Have a haematological malignancy
- Have had a jejunoileal bypass
- Have chronic renal failure or receive haemodialysis
- Have had a gastrectomy
- Are receiving anti-tumour necrosis factor (TNF)-alpha treatment
- Have silicosis

Patients in these groups should be advised of the risks and symptoms of TB, on the basis of an individual risk assessment basis, usually in a standard letter of the type referred to as "inform and advise" information.

Prevention and Control

BCG Vaccination

Overview (Overall Recommendations)

D(GPP) - When BCG is being recommended, the benefits and risks of vaccination and remaining unvaccinated should be discussed with the person (or, if a child, with the parents), so that they can make an informed decision. This discussion

should be tailored to the person, be in an appropriate language, and take into account cultural sensitivities and stigma.

D(GPP) - People identified for BCG vaccination through occupational health, contact tracing, or new entrant screening who are also considered to be at increased risk of being HIV positive, should be offered HIV testing before BCG vaccination. (See previous section for details of further action in HIV-positive patients.)

For Neonates

D(GPP) - Neonatal BCG vaccination for any baby at increased risk of TB should be discussed with the parents or legal guardian.

D(GPP) - Primary care organisations with a high incidence of TB (as defined by the HPA; go to www.hpa.org.uk and search for "tuberculosis rate bands") should consider vaccinating all neonates soon after birth.

D(GPP) - In areas with a low incidence of TB (as defined by the HPA; go to www.hpa.org.uk and search for 'tuberculosis rate bands'), primary care organisations should offer BCG vaccination to selected neonates who:

- Were born in an area with a high incidence of TB (as defined by the HPA; go to www.hpa.org.uk and search for "tuberculosis rate bands"), or
- Have one or more parents or grandparents who were born in a high-incidence country (go to www.hpa.org.uk and search for "WHO country data TB"), or
- Have a family history of TB in the past five years

D(GPP) - Mantoux testing should not be done routinely before BCG vaccination in children younger than six years.

For Infants and Older Children

Routine BCG vaccination is not recommended for children aged 10 to 14.

- **C** - Healthcare professionals should opportunistically identify unvaccinated children older than four weeks and younger than two years at increased risk of TB (see section 10.2 in the full version of the original guideline document) who would have qualified for neonatal BCG and provide Mantoux testing and BCG (if Mantoux negative).
- **D(GPP)** - This opportunistic vaccination should be in line with the Chief Medical Officer's advice (www.dh.gov.uk/assetRoot/04/11/81/35/04118135.pdf) on vaccinating this age group following the end of the school-based programme

D(GPP) - Mantoux testing should not be done routinely before BCG vaccination in children younger than six years unless they have a history of residence or prolonged stay (more than one month) in a country with a high incidence of TB.

For New Entrants from High-Incidence Countries

Readers should also be aware of the recommendations under new entrant screening (see below). This process should include Mantoux tests on appropriate new entrants and risk assessment for HIV prior to vaccination.

BCG vaccination should be offered to Mantoux-negative new entrants who:

- **B** - Are from high-incidence countries, (go to www.hpa.org.uk and search for "WHO country data TB") *and*
- **B** - Are previously unvaccinated (that is, without adequate documentation or a characteristic scar), *and*
- **D(GPP)** - Are aged 35 or younger. (Note: The draft 2006 Green Book recommends BCG for new entrants only up to the age of 16. However in this guideline BCG is recommended for those up to 35 years who come from the countries with the very highest rates of TB because there is some evidence of cost-effectiveness.)

For Healthcare Workers

D(GPP) - BCG vaccination should be offered to healthcare workers, irrespective of age, who:

- Are previously unvaccinated (that is, without adequate documentation or a characteristic scar), *and*
- Will have contact with patients or clinical materials, *and*
- Are Mantoux (or interferon-gamma) negative

BCG Vaccination for Contacts of People with Active Tuberculosis

D(GPP) - BCG vaccination should be offered to Mantoux-negative contacts of people with respiratory TB (see section "Contract Tracing: Human to Human Transmission" below for details of contact tracing) if they are previously unvaccinated (that is, without adequate documentation or a characteristic scar) and are:

- Aged 35 or younger
- Aged 36 and older and a healthcare or laboratory worker who has contact with patients or clinical materials (see previous section)

Other Groups

D(GPP) - BCG vaccination should be offered to previously unvaccinated, Mantoux-negative people under 35 in the following groups at increased risk of exposure to TB, in accordance with the "Green Book": (Department of Health, 2006)

- Veterinary and other staff such as abattoir workers who handle animal species known to be susceptible to TB, such as simians
- Prison staff working directly with prisoners
- Staff of care homes for elderly people
- Staff of hostels for homeless people and facilities accommodating refugees and asylum seekers

- People going to live or work with local people for more than 1 month in a high-incidence country. (go to www.hpa.org.uk and search for "WHO country data TB")

See "For Healthcare Workers" above for advice on healthcare workers.

Active Case Finding

Contact Tracing: Human-to-Human Transmission

D(GPP) - Once a person has been diagnosed with active TB, the diagnosing physician should inform relevant colleagues so that the need for contact tracing can be assessed without delay. Contact tracing should not be delayed until notification.

D(GPP) - Screening should be offered to the household contacts of any person with active TB, irrespective of the site of infection. Household contacts are defined as those who share a bedroom, kitchen, bathroom, or sitting room with the index case. Screening should comprise:

- Standard testing for latent TB for those aged 35 or younger, and consideration of BCG or treatment for latent TB infection once active TB has been ruled out
- Interferon-gamma test six weeks after the Mantoux test, and consideration of BCG or treatment for latent TB infection once active TB has been ruled out, for those who:
    - Are previously unvaccinated *and*
    - Are household contacts of a person with sputum smear-positive TB *and*
    - Are Mantoux negative (<6 mm)
- Chest x-ray (if there are no contraindications) for those older than 35, possibly leading to further investigation for active TB

D(GPP) - For people with sputum smear-positive TB, other close contacts should be assessed. These may include boyfriends or girlfriends and frequent visitors to the home of the index case. Occasionally, a workplace associate may be judged to have had contact equivalent to that of household contacts, and should be assessed in the same way.

C - Casual contacts of people with TB, who will include the great majority of workplace contacts, should not normally be assessed.

D(GPP) - The need for tracing casual contacts of people with TB should be assessed if:

- The index case is judged to be particularly infectious (for example, evidenced by transmission to close contacts), *or*
- Any casual contacts are known to possess features that put them at special risk of infection (See "Management of Latent Tuberculosis" above)

D(GPP) - "Inform and advise" information should be offered to all contacts of people with smear-positive TB.

Contact Tracing: Cattle-to-Human Transmission

D(GPP) - "Inform and advise" information should be given to people in contact with TB-diseased animals. Diagnostic tests for latent TB should be considered only for children younger than 16 who have not had BCG vaccination and have regularly drunk unpasteurised milk from animals with TB udder lesions.

Contact Tracing: Cases on Aircraft

D(GPP) - Following diagnosis of TB in an aircraft traveller, contact tracing of fellow passengers should not routinely be undertaken.

D(GPP) - The notifying clinician should inform the relevant consultant in communicable disease control (CCDC) if:

- **D(GPP)** - Less than three months has elapsed since the flight and the flight was longer than eight hours, *and*
- **D(GPP)** - The index case is sputum smear positive, *and*
- **C** - The index case has MDR TB, *or*
- **D(GPP)** - The index case coughed frequently during the flight.

D(GPP) - The CCDC should provide the airline with "inform and advise" information to send to passengers seated in the same part of the aircraft as the index case. (Note: Published evidence does not allow for a precise definition, but such contact tracing on aircraft has often only included people within three rows on either side of the index case.)

D(GPP) - If the TB index case is an aircraft crew member, contact tracing of passengers should not routinely take place.

B - If the TB index case is an aircraft crew member, contact tracing of other members of staff is appropriate, in accordance with the usual principles for screening workplace colleagues. (See "Contact Tracing: Human to Human Transmission" above)

Contact Tracing: Cases in Schools

D(GPP) - Following diagnosis of TB in a school pupil or member of staff, the CCDC should be prepared to explain the prevention and control procedures to staff, parents and the press. Advice on managing these incidents and their public relations is available from the Health Protection Unit (HPU).

B - If a school pupil is diagnosed with sputum smear-positive TB, the rest of his or her class (if there is a single class group), or the rest of the year group who share classes, should be assessed as part of contact tracing.

C - If a teacher has sputum smear-positive TB, the pupils in his or her classes during the preceding three months should be assessed as part of contact tracing.

D(GPP) - Clinicians conducting contact tracing in a school should consider extending it to include children and teachers involved in extracurricular activities, and non-teaching staff, on the basis of:

- The degree of infectivity of the index case
- The length of time the index case was in contact with others
- Whether contacts are unusually susceptible to infection
- The proximity of contact

Secondary cases of sputum smear-positive TB should be treated as index cases for contact tracing (see recommendations above for class of recommendation).

D(GPP) - If the index case of a school pupil's TB infection is not found, and the child is not in a high-risk group for TB, contact tracing and screening (by either symptom enquiry or chest x-ray) should be considered for all relevant members of staff at the school.

Contact Tracing: Community Childcare

D(GPP) - When an adult who works in childcare is diagnosed with sputum smear-positive TB, management is as for contact tracing (see "Contact Tracing: Human-to-Human Transmission" above).

Contact Tracing: Cases in Hospital Inpatients

D(GPP) - Following diagnosis of TB in a hospital inpatient, a risk assessment should be undertaken. This should take in to account:

- The degree of infectivity of the index case
- The length of time before the infectious patient was isolated
- Whether other patients are unusually susceptible to infection
- The proximity of contact

Contact tracing and testing should be carried out only for patients for whom the risk is regarded as significant.

D(GPP) - Patients should be regarded as at risk of infection if they spent more than eight hours in the same bay as an inpatient with sputum smear-positive TB who had a cough. The risk should be documented in the contact's clinical notes, for the attention of the contact's consultant. The contact should be given "inform and advise" information, and their general practitioner should be informed.

D(GPP) - If patients were exposed to a patient with sputum smear-positive TB for long enough to be equivalent to household contacts (as determined by the risk assessment), or an exposed patient is known to be particularly susceptible to infection, they should be managed as equivalent to household contacts (see "Contact Tracing: Human-to-Human Transmission" above).

D(GPP) - If an inpatient with sputum smear-positive TB is found to have MDR TB, or if exposed patients are HIV positive, contact tracing should be in line with the Interdepartmental Working Group on Tuberculosis guidelines (Interdepartmental Working Group on Tuberculosis, 1998)

D(GPP) - In cases of doubt when planning contact tracing after diagnosing sputum smear-positive TB in an inpatient, further advice should be sought from the regional or national Health Protection Agency and/or people experienced in the field.

New Entrants (People Recently Arriving in or Returning to the UK)

Healthcare professionals, including primary care staff, responsible for screening new entrants* should maintain a coordinated programme to:

- **B** - Detect active TB and start treatment.
- **B** - Detect latent TB and start treatment.
- **D(GPP)** - Provide BCG vaccination to those in high-risk groups who are not infected and who are previously unvaccinated.
- **D(GPP)** - Provide relevant information to all new entrants

*Note: In this guideline, new entrants are defined as people who have recently arrived in or returned to the UK from high-incidence countries, as defined by the HPA; go to www.hpa.org.uk and search for "WHO country data TB".

D(GPP) - New entrant screening for tuberculosis should be incorporated within larger health screening programmes for new entrants, linked to local services.

D(GPP) - Assessment for, and management of, TB in new entrants should consist of the following.

- A chest x-ray for those who have not had one recently taken, unless they are younger than 11 or are possibly pregnant
- Clinical assessment for those with an abnormal chest x-ray
- Risk assessment for HIV, including HIV prevalence rates in the country of origin, which is then taken into account for Mantoux testing and BCG vaccination
- A Mantoux test for people with normal recent chest x-ray who are:
    - Younger than 16, *or*
    - Aged 16 to 35, from sub-Saharan Africa or a country with a TB incidence greater than 500 per 100,000
- A Mantoux test for:
    - Children younger than 11 years
    - Pregnant women
- Interferon-gamma test (if available) if Mantoux test positive (6 mm or greater) in someone who has not had BCG vaccination, or strongly positive (15 mm or greater) in someone who has been vaccinated.
- Assessment for active TB if interferon-gamma test is positive; interpret chest x-ray first if it is not contraindicated.
- Treatment for latent TB infection for people aged 35 or younger in whom active TB has been excluded, with a positive Mantoux test inconsistent with

their BCG history, and a positive interferon-gamma test (if this test was available), and who are:
    - Younger than 16, *or*
    - Aged 16 to 35, from sub-Saharan Africa or a country with a TB incidence greater than 500/100,000
- Consideration of BCG for unvaccinated people who are Mantoux negative (see section on "BCG Vaccination for New Entrants from High-Incidence Countries" above).
- "Inform and advise" information for people who do not have active TB and are not being offered BCG or treatment for latent TB infection.

See the algorithm in Figure 10 in the full version of the original guideline document for further detail.

New entrants should be identified for TB screening from the following information:

- **D(GPP)** - Port of arrival reports
- **B** - New registrations with primary care
- **D(GPP)** - Entry to education (including universities)
- **D(GPP)** - Links with statutory and voluntary groups working with new entrants

D(GPP) - Any healthcare professional working with new entrants should encourage them to register with a GP.

Street Homeless People

D(GPP) - Active case finding should be carried out among street homeless people (including those using direct access hostels for the homeless) by chest x-ray screening on an opportunistic and/or symptomatic basis. Simple incentives for attending, such as hot drinks and snacks, should be considered.

D(GPP) - Healthcare professionals working with people with TB should reinforce and update education about TB, and referral pathways, to primary care colleagues, social workers, and voluntary workers who work with homeless people.

Preventing Infection in Specific Settings

Healthcare Environments: New Employees

D(GPP) - Employees new to the NHS who will be working with patients or clinical specimens should not start work until they have completed a TB screen or health check, or documentary evidence is provided of such screening having taken place within the preceding 12 months.

D(GPP) - Employees new to the NHS who will not have contact with patients or clinical specimens should not start work if they have signs or symptoms of TB.

D(GPP) - Health checks for employees new to the NHS who will have contact with patients or clinical materials should include:

- Assessment of personal or family history of TB
- Symptom and signs enquiry, possibly by questionnaire
- Documentary evidence of TB skin testing (or interferon-gamma testing) and/or BCG scar check by an occupational health professional, not relying on the applicant's personal assessment
- Mantoux result within the last five years, if available

D(GPP) - If an employee new to the NHS has no (or inconclusive) evidence of prior BCG vaccination, a Mantoux or interferon-gamma test (see "Diagnosing Latent Tuberculosis" above) should be performed.

D(GPP) - Employees who will be working with patients or clinical specimens and who are Mantoux negative (less than 6 mm) should have an individual risk assessment for HIV infection before BCG vaccination is given.

D(GPP) - Employees new to the NHS should be offered BCG vaccination, whatever their age, if they will have contact with patients and/or clinical specimens, are Mantoux negative (less than 6 mm), and have not been previously vaccinated. (See "For Healthcare Workers" above for more detail.)

D(GPP) - Employees of any age who are new to the NHS and are from countries of high TB incidence, or who have had contact with patients in settings with a high TB prevalence should have a Mantoux test. If negative (less than 6 mm), the two preceding recommendations should be followed. If positive (6 mm or greater), the person should be referred for clinical assessment for diagnosis and possible treatment of latent infection or active disease.

D(GPP) - If a new employee from the UK or other low-incidence setting, without prior BCG vaccination, has a positive Mantoux or interferon-gamma test, they should have a medical assessment and a chest x-ray. They should be referred to a TB clinic for consideration of TB treatment if the chest x-ray is abnormal, or for consideration of treatment of latent TB infection if the chest x-ray is normal.

D(GPP) - If a prospective or current healthcare worker who is Mantoux negative (less than 6 mm), declines BCG vaccination, the risks should be explained and the oral explanation supplemented by written advice. If the person still declines BCG vaccination, he or she should not work where there is a risk of exposure to TB. The employer will need to consider each case individually, taking account of employment and health and safety obligations.

D(GPP) - Clinical students, agency and locum staff, and contract ancillary workers who have contact with patients or clinical materials should be screened for TB to the same standard as new employees in healthcare environments, according to the recommendations set out above. Documentary evidence of screening to this standard should be sought from locum agencies and contractors who carry out their own screening.

D(GPP) - NHS trusts arranging care for NHS patients in non-NHS settings should ensure that healthcare workers who have contact with patients or clinical materials in these settings have been screened for TB to the same standard as new employees in healthcare environments (See the first two recommendations in this section).

Healthcare Environments: Occupational Health

These recommendations set the standard for NHS organisations and therefore should apply in any setting in England and Wales where NHS patients are treated.

D(GPP) - Reminders of the symptoms of TB, and the need for prompt reporting of such symptoms, should be included with annual reminders about occupational health for staff who:

- Are in regular contact with TB patients or clinical materials, *or*
- Have worked in a high-risk clinical setting for four weeks or longer

One-off reminders should be given after a TB incident on a ward.

D(GPP) - If no documentary evidence of prior screening is available, staff in contact with patients or clinical material who are transferring jobs within the NHS should be screened as for new employees (see "Healthcare Environments: New Employees" above).

D(GPP) - The risk of TB for a new healthcare worker who knows he or she is HIV positive at the time of recruitment should be assessed as part of the occupational health checks.

D(GPP) - The employer, through the occupational health department, should be aware of the settings with increased risk of exposure to TB, and that these pose increased risks to HIV-positive healthcare workers.

D(GPP) - Healthcare workers who are found to be HIV positive during employment should have medical and occupational assessments of TB risk, and may need to modify their work to reduce exposure.

Prisons and Remand Centres

D(GPP) - Healthcare workers providing care for prisoners and remand centre detainees should be aware of the signs and symptoms of active TB (see "Diagnosing Active Tuberculosis" above). TB services should ensure that awareness of these signs and symptoms is also promoted among prisoners and prison staff.

Prisoners should be screened for TB by:

- **D(GPP)** - A health questionnaire on each entry to the prison system, *then*
- **C** - For those with signs and symptoms of active TB, a chest x-ray
- **D(GPP)** - and three sputum samples taken in 24 hours for TB microscopy, including a morning sputum sample (see "Diagnosing Active Tuberculosis" above)

D(GPP) - All prisoners receiving treatment for active or latent TB should receive DOT.

D(GPP) - Prison medical services should have liaison and handover arrangements to ensure continuity of care before any prisoner on TB treatment is transferred between prisons.

D(GPP) - If a prisoner is being treated for active or latent TB, the prison medical services should draw up as early as possible a contingency plan for early discharge, which could happen directly from a court appearance. This plan should include firm arrangements for clinical follow-up and treatment monitoring in the intended district of residence, and should take into account that there may not be a fixed residence arranged for the prisoner after release. The prisoner should be given contact details for a named key worker, who will visit and monitor the prisoner after release and liaise between services involved.

D(GPP) - Prison service staff and others who have regular contact with prisoners (for example, probation officers and education and social workers) should have pre- and on-employment screening at the same level as for healthcare workers with patient contact (see "Healthcare Environments: New Employees" and "Healthcare Environments: Occupational Health" above).

Definitions:

Levels of Evidence for Intervention Studies

1^{++} High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1^{+} Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1^{-} Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2^{++} High-quality systematic reviews of case–control or cohort studies. High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2^{+} Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2^{-} Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytical studies (for example, case reports, case series)

4 Expert opinion, formal consensus

Levels of Evidence for Studies of the Accuracy of Diagnostic Tests

Ia Systematic review (with no or minor variations in the directions and degrees of results between studies) of level-1 studies, which are studies that use:

- A blind comparison of the test with a validated reference standard (gold standard)
- A sample of patients that reflects the population to whom the test would apply

Ib Level-1 studies

II Level-2 studies, which are studies that have only one of the following:

- The population is narrow (the sample does not reflect the population to whom the test would apply).
- A poor reference standard is used (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference').
- The comparison between the test and reference standard is not blind.
- The study is a case-control study.

Systematic reviews of level-2 studies

III Level-3 studies, which are studies that have at least two of the features listed for level-2 studies *or*

Systematic reviews of level-3 studies

IV Expert committee reports, opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research, or 'first principles'

Classification of Recommendations on Interventions

A At least one meta-analysis, systematic review, or randomised controlled trial (RCT) that is rated as 1^{++}, and is directly applicable to the target population, *or*
A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1^{+}, is directly applicable to the target population, and demonstrates overall consistency of results, *or*
Evidence drawn from a NICE technology appraisal

B A body of evidence that includes studies rated as 2^{++}, is directly applicable to the target population, and demonstrates overall consistency of results, *or*
Extrapolated evidence from studies rated as 1^{++} or 1^{+}

C A body of evidence that includes studies rated as 2^{+}, is directly applicable to the target population, and demonstrates overall consistency of results, *or*
Extrapolated evidence from studies rated as 2^{++}

D Evidence level 3 or 4, *or*
Extrapolated evidence from studies rated as 2^{+}, *or*
Formal consensus

D(GPP) A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group *or* extrapolated from level 2 clinical evidence, supplemented with health-economic modelling

Classification of Recommendations on Diagnostic Tests

A(DS) Studies with level of evidence Ia or Ib

B(DS) Studies with level of evidence II

C(DS) Studies with level of evidence III

D(DS) Studies with level of evidence IV

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Isolation decisions for patients with suspected respiratory tuberculosis (TB)
- Testing and treating asymptomatic children aged between 4 weeks and 2 years old who are contacts of people with sputum smear-positive TB
- Asymptomatic household and other close contacts of all cases of active TB
- New entrant screening
- New National Health Service employees

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Implementation of the guideline recommendation will lead to improved diagnosis of primary cases of tuberculosis (TB), identification of secondary cases, treatment of active disease, control of latent infection, and prevention of further transmission. At a population level, the combined result of these activities should be to curb and then reverse the increase in TB seen in England and Wales in recent years.

POTENTIAL HARMS

Adverse effects of drug therapy and reactions to Bacille Calmette-Guerin (BCG) vaccination

CONTRAINDICATIONS

CONTRAINDICATIONS

Bacille Calmette Guerin (BCG) is a live vaccine and as such is contraindicated in a number of situations where the immune system may be compromised, particularly if the person is known or suspected to be human immunodeficiency virus (HIV) positive, because of the risk of generalised BCG infection.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Guideline Limitations

These include:

- The diagnosis and treatment chapters of this guideline (5–10 in the original guideline document), except rapid diagnostic techniques (5.3 and 5.4 in the original guideline document), do not cover issues of service delivery, organisation, or provision (as this was not specified in the remit from the Department of Health).
- The National Institute for Health and Clinical Excellence (NICE) is primarily concerned with health services and so recommendations are not provided for Social Services and the voluntary sector. However, the guideline may address important issues in how National Health Service (NHS) clinicians interface with these other sectors.
- Generally the guideline does not cover rare, complex, complicated or unusual conditions.

Disclaimer

Healthcare providers need to use clinical judgement, knowledge, and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioner in light of individual patient circumstances, the wishes of the patient, clinical expertise, and resources.

The British National Formulary (BNF) should be consulted alongside any drug recommendations cited in this guideline and note taken of the indications, contraindications, cautions, and product characteristics.

NICE guidelines will normally only make drug recommendations that fall within licensed indications. If a drug is recommended outside of its licensed indication, this will be made clear in the guideline. This guideline contains recommendations for prescribing the following, all of which are within current licensed indications:

- Ethambutol, for treating active tuberculosis (TB)
- Isoniazid, for treating both latent and active TB

- Pyrazinamide, for treating active TB
- Rifampicin, for treating both latent and active TB
- Streptomycin, for treating isoniazid mono-resistant active TB
- Any glucocorticoid, for treating inflammation associated with active TB of the meninges or central nervous system (CNS)

The National Collaborating Centre for Chronic Conditions (NCC-CC) disclaims any responsibility for damages arising out of the use or non-use of these guidelines and the literature used in support of these guidelines.

Other

The guideline is designed for use in the National Health Service in England and Wales. Readers in other countries, particularly where the incidence of TB is higher, should exercise caution before applying the recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Key Priorities for Implementation

The following recommendations have been identified as priorities for implementation.

Management of Active Tuberculosis (TB)

A 6-month, four-drug initial regimen (6 months of isoniazid and rifampicin supplemented in the first 2 months with pyrazinamide and ethambutol) should be used to treat active respiratory TB in:

- Adults not known to be human immunodeficiency virus (HIV)-positive
- Adults who are HIV-positive
- Children

This regimen is referred to as "standard recommended regimen" in this guideline.

Patients with active meningeal TB should be offered:

- A treatment regimen, initially lasting for 12 months, comprising isoniazid, pyrazinamide, rifampicin, and a fourth drug (for example, ethambutol) for the first 2 months, followed by isoniazid and rifampicin for the rest of the treatment period
- A glucocorticoid at the normal dose range
    - Adults – equivalent to prednisolone 20 to 40 mg if on rifampicin, otherwise 10 to 20 mg
    - Children – equivalent to prednisolone 1 to 2 mg/kg, maximum 40 mg

  with gradual withdrawal of the glucocorticoid considered, starting within 2–3 weeks of initiation.

Improving Adherence

Use of directly observed therapy (DOT) is not usually necessary in the management of most cases of active TB. All patients should have a risk assessment for adherence to treatment, and DOT should be considered for patients who have adverse factors on their risk assessment, in particular:

- Street- or shelter-dwelling homeless people with active TB
- Patients with likely poor adherence, in particular those who have a history of non-adherence

The TB service should tell each person with TB who their named key worker is, and how to contact them. This key worker should facilitate education and involvement of the person with TB in achieving adherence.

New Entrant Screening

New entrants should be identified for TB screening from the following information:

- Port of Arrival reports
- New registrations with primary care
- Entry to education (including universities)
- Links with statutory and voluntary groups working with new entrants

BCG (Bacille Calmette Guerin) Vaccination

Neonatal BCG vaccination for any baby at increased risk of TB should be discussed with the parents or legal guardian.

Primary care organisations with a high incidence of TB should consider vaccinating all neonates soon after birth.

Implementation in the National Health Service (NHS)

The Healthcare Commission will assess the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004.

Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

This guideline is supported by the following implementation tools available on the NICE Web site (see "Availability of Companion Documents" field).

- A slide set – key messages for local discussion.
- Costing tools:
    - A national costing report, which estimates the overall resource impact associated with implementation
    - A local costing template; a simple spreadsheet that can be used to estimate the local cost of implementation.

- Implementation advice – practical suggestions on how to address potential barriers to implementation.

Suggested audit criteria based on the key priorities for implementation are listed in appendix D of the NICE version of the guideline (see "Availability of Companion Documents" field), and can be used to audit practice locally.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Chronic Conditions. Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control. London (UK): Royal College of Physicians; 2006. 215 p. [386 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Chronic Conditions - National Government Agency [Non-U.S.]

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National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Guideline Development Group declared any interests in accordance with the National Institute for Health and Clinical Excellence (NICE) technical manual. A register is available from the National Collaborating Centre for Chronic Conditions (NCC-CC) for inspection upon request (ncc-cc@rcplondon.ac.uk).

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- National Collaborating Centre for Chronic Conditions. Tuberculosis. Clinical diagnosis and management of tuberculosis, and measures for its prevention and control. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Mar. 66 p. (Clinical guideline; no. 33). Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Tuberculosis. Clinical diagnosis and management of tuberculosis, and measures for its prevention and control. Quick reference guide. National Collaborating Centre for Chronic Conditions, 2006 Mar. 23 p. Electronic copies: Available from the NICE Web site.
- National Institute for Health and Clinical Excellence. Implementation advice. Suggested actions for implementing the NICE clinical guideline on tuberculosis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Mar. 23 p. Electronic copies: Available from the NICE Web site.
- Tuberculosis (TB): clinical diagnosis and management of tuberculosis and measures for its prevention and control. London (UK): National Institute for

Health and Clinical Excellence (NICE); 2006 Mar. 22 p. Electronic copies: Available from the NICE Web site.

- Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control. Costing report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Mar. 37 p. Electronic copies: Available from the NICE Web site.
- Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control. Costing template. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Mar. Various p. Electronic copies: Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1008. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix D of the NICE version of the original guideline document.

PATIENT RESOURCES

The following is available:

- Preventing and treating tuberculosis. Understanding NICE guidance – information for people who have tuberculosis or are being tested for it, their families and carers, and the public. National Institute for Health and Clinical Excellence (NICE), 2006 Mar. 23 p.

Electronic copies: Available from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS), 11 Strand, London, WC2N 5HR. Response Line 0870 1555 455, ref N1009.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on July 18, 2006. The information was verified by the guideline developer on September 29, 2006.

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